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EXAMINER	
SCHLAPKOHL, WALTER	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,264	RONINSON ET AL.	
	Examiner	Art Unit	
	Walter Schlapkohl	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-107* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-107* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8 and 26-29, drawn to a method comprising identifying a compound that induces senescence when expression of at least one gene is higher in the presence of the compound, classified in class 435, subclass 7.2.

Group I is comprised of multiple independent and/or distinct inventions recited in the alternative which are the products or methods drawn to different genes/promoters which do not render obvious each other and thus are patentably distinct. Applicant must elect a single invention which is the product or method drawn to one specific gene/promoter to which the claims will be restricted. Applicant must also indicate which claims are readable on the elected invention. This is not an election of species because the genes/promoters are different and distinct and thus the methods drawn to different and distinct genes are different and distinct inventions from each other.

II. Claims 9-12 and 30-33, drawn to a method comprising identifying compounds that induce senescence when

expression of at least one gene is higher in the presence of the compound, and further comprising identifying a compound wherein expression of a gene set is not greater in the presence of the compound, classified in class 435, subclass 7.2.

Group II is comprised of multiple independent and/or distinct inventions recited in the alternative which are the products or methods drawn to different genes/promoters per method step which do not render obvious each other and thus are patentably distinct. Applicant must elect a single invention which is the product or method drawn to one specific gene/promoter per method step to which the claims will be restricted. Applicant must also indicate which claims are readable on the elected invention. This is not an election of species because the genes/promoters are different and distinct and thus the methods drawn to different and distinct genes are different and distinct inventions from each other.

III. Claims 13-20 and 34-37, drawn a method comprising assaying for cell growth and morphological features of senescence, and further comprising identifying a compound wherein expression of at least one gene is greater in the presence of the compound, classified in class 435, subclass 7.2.

Group III is comprised of multiple independent and/or distinct inventions recited in the alternative which are the products or methods drawn to different genes/promoters which do not render obvious each other and thus are patentably distinct. Applicant must elect a single invention which is the product or method drawn to one specific gene/promoter to which the claims will be restricted. Applicant must also indicate which claims are readable on the elected invention. This is not an election of species because the genes/promoters are different and distinct and thus the methods drawn to different and distinct genes are different and distinct inventions from each other.

IV. Claims 21-25, 38-41 and 50, drawn to a method comprising assaying for cell growth and morphological features of senescence and further comprising identifying compounds wherein expression of a gene set is not greater in the presence of the compound, and further comprising identifying a compound wherein expression of a gene set is not greater in the presence of the compound, classified in class 435, subclass 7.2.

Group IV is comprised of multiple independent and/or distinct inventions recited in the alternative which are the products or methods drawn to different genes/promoters which do

not render obvious each other and thus are patentably distinct. Applicant must elect a single invention which is the product or method drawn to one specific gene/promoter per method step to which the claims will be restricted. Applicant must also indicate which claims are readable on the elected invention. This is not an election of species because the genes/promoters are different and distinct and thus the methods drawn to different and distinct genes are different and distinct inventions from each other.

V. Claims 42-49 and 68-71, drawn to a method comprising identifying a compound that induces senescence when expression of at least one gene is lower in the presence of the compound, classified in class 435, subclass 7.2.

Group V is comprised of multiple independent and/or distinct inventions recited in the alternative which are the products or methods drawn to different genes/promoters which do not render obvious each other and thus are patentably distinct. Applicant must elect a single invention which is the product or method drawn to one specific gene/promoter to which the claims will be restricted. Applicant must also indicate which claims are readable on the elected invention. This is not an election of species because the genes/promoters are different and

distinct and thus the methods drawn to different and distinct genes are different and distinct inventions from each other.

VI. Claims 51-54, 63 and 72-75, drawn to a method comprising identifying a compound that induces senescence when expression of at least one gene is lower in the presence of the compound, and further comprising identifying a compound wherein expression of a gene set is not greater in the presence of the compound, classified in class 435, subclass 7.2.

Group VI is comprised of multiple independent and/or distinct inventions recited in the alternative which are the products or methods drawn to different genes/promoters which do not render obvious each other and thus are patentably distinct. Applicant must elect a single invention which is the product or method drawn to one specific gene/promoter per method step to which the claims will be restricted. Applicant must also indicate which claims are readable on the elected invention. This is not an election of species because the genes/promoters are different and distinct and thus the methods drawn to different and distinct genes are different and distinct inventions from each other.

VII. Claims 55-62 and 76-79 drawn to a method comprising assaying for cell growth and morphological features of

senescence, and further comprising identifying a compound that induces senescence when expression of at least one gene is lower in the presence of the compound, classified in class 435, subclass 7.2.

Group VII is comprised of multiple independent and/or distinct inventions recited in the alternative which are the products or methods drawn to different genes/promoters which do not render obvious each other and thus are patentably distinct. Applicant must elect a single invention which is the product or method drawn to one specific gene/promoter to which the claims will be restricted. Applicant must also indicate which claims are readable on the elected invention. This is not an election of species because the genes/promoters are different and distinct and thus the methods drawn to different and distinct genes are different and distinct inventions from each other.

VIII. Claims 64-67 and 80-83, drawn to a method comprising assaying for cell growth and morphological features of senescence, and further comprising identifying a compound that induces senescence when expression of at least one gene is lower in the presence of the compound, and further comprising identifying a compound wherein expression of a gene set is not

greater in the presence of the compound, classified in class 435, subclass 7.2.

Group VIII is comprised of multiple independent and/or distinct inventions recited in the alternative which are the products or methods drawn to different genes/promoters which do not render obvious each other and thus are patentably distinct. Applicant must elect a single invention which is the product or method drawn to one specific gene/promoter per method step to which the claims will be restricted. Applicant must also indicate which claims are readable on the elected invention. This is not an election of species because the genes/promoters are different and distinct and thus the methods drawn to different and distinct genes are different and distinct inventions from each other.

IX. Claims 84-85, drawn to a compound that induces senescence in a mammalian cell, classified in class 514, subclass 1.

X. Claims 86-94, drawn to a method of assessing efficacy of a treatment of a disease or condition related to abnormal cell proliferation or neoplastic cell growth, classified in class 424, subclass 9.2.

Group X is comprised of multiple independent and/or distinct inventions recited in the alternative which are the

products or methods drawn to different genes which do not render obvious each other and thus are patentably distinct. Applicant must elect a single invention which is the product or method drawn to one specific gene to which the claims will be restricted. Applicant must also indicate which claims are readable on the elected invention. This is not an election of species because the genes are different and distinct and thus the methods drawn to different and distinct genes are different and distinct inventions from each other.

XI. Claims 95-96, drawn to a method of treating a disease, classified in class 424, subclass 897.

XII. Claims 97-103, drawn to a method of identifying a compound that inhibits senescence-associated induction of cellular gene expression, classified in class 435, subclass 7.2.

Group XII is comprised of multiple independent and/or distinct inventions recited in the alternative which are the products or methods drawn to different genes which do not render obvious each other and thus are patentably distinct. Applicant must elect a single invention which is the product or method drawn to one specific gene to which the claims will be restricted. Applicant must also indicate which claims are readable on the elected invention. This is not an election of

species because the genes are different and distinct and thus the methods drawn to different and distinct genes are different and distinct inventions from each other.

XIII. Claims 104-107, drawn to a method of identifying a compound that inhibits senescence-associated induction of cellular gene expression, further comprising producing a recombinant mammalian cell, classified in class 435, subclass 7.2.

Group XIII is comprised of multiple independent and/or distinct inventions recited in the alternative which are the products or methods drawn to different promoters which do not render obvious each other and thus are patentably distinct. Applicant must elect a single invention which is the product or method drawn to one specific promoter to which the claims will be restricted. Applicant must also indicate which claims are readable on the elected invention. This is not an election of species because the promoters are different and distinct and thus the methods drawn to different and distinct genes are different and distinct inventions from each other.

Note: the non-standard format of this restriction, separating the inventions into multi-invention groups drawn to distinct types of products and methods, followed by an election of a single invention drawn to one gene/promoter within the

elected multi-invention group was done for the sake of compactness of the communication and clarity, instead of using the more standard format setting forth each separate invention drawn to each separate gene/promoter which would require a much longer and less clear communication.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-VIII and X-XIII are biologically and functionally distinct from each other and thus one does not render the other obvious. The methods of Groups I-VIII and X-XII comprise steps which are not required for or present in the methods of the other groups: identifying a compound that induces senescence when expression of at least one gene is higher in the presence of the compound (Group I), identifying a compound that induces senescence when expression at least one gene is not greater in the presence of the compound (Group II), assaying for cell growth and morphological features of senescence (Group III), the method of Group III further comprising the step of identifying a compound that induces senescence when expression of at least one gene is not greater in the presence of the compound (Group IV), identifying a compound that induces senescence when expression of at least one

gene is lower in the presence of the compound (Group V), the method of Group V further comprising the step of identifying a compound that induces senescence when expression of at least one gene is not greater in the presence of the compound (Group VI), the method of Group V further comprising the step of assaying for cell growth a morphological features of senescence (Group VII), the method of Group VII further comprising the step of identifying a compound that induces senescence when expression of at least one gene is not greater in the presence of the compound (Group VIII), assessing efficacy of a treatment of a disease or condition (Group X), treating a disease (Group XI), identifying a compound as an inhibitor of senescence-associated induction of cellular gene expression (Group XII), the method of Groups XII further comprising the step of producing a recombinant mammalian cell (Group XIII). Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by the requirement for separate searches based upon their

biological and functional properties, restriction for examination purposes as indicated is proper.

The inventions of Group IX and Groups XI-XIII are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the compound of Group IX can be used in any number of different methods as evidenced by its use in the distinct inventions of Groups XI-XIII.

Searching the inventions of Group IX and Groups XI-XIII together would impose a serious search burden. The inventions of Group IX and Groups XI-XIII have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for a compound and a method of treating disease or the method of inhibiting senescence-associated induction of gene expression or the method comprising identifying a compound that induces senescence are not coextensive.

The inventions of Group IX and Groups I-VIII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 806.01). In the instant case, the product of Group IX is not used in or made by the methods of Group I-VIII and X.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as show by their different classifications and the requirement for separate searches based upon their biological and functional properties, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

1. A mammalian cell to be cultured in the presence or absence of a compound that induces senescence. If one of Groups I-VIII or XII is elected, then the species applies and Applicant must elect from either a tumor cell (e.g. claim 2) or a p53-deficient cell (e.g. claim 3).

2. A method of detecting expression of the cellular gene. If one of Groups I-VIII, X, XII or XIII is elected, then the species applies and Applicant must elect a method to detect a

change in gene expression. For example, choose from claims 4-6, or 8.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 84-85 and 95-96 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or

identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter A. Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office.)

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

October 2, 2005

TERRY MCKELVEY
PRIMARY EXAMINER